REMARKS

Applicants have amended claims 19 and 37 in response to the Examiner's recommendation at page 5 of the Office Action to expedite prosecution and to make explicit that which was implicit, namely that the surface modified powder is prepared in the absence of any solvent. This amendment is supported by the original claims, as well as pages 6 – 8 of the specification. Claim 32 has been amended to correct a minor typographical error. As such, these amendments do not introduce any new matter and their entry is respectfully requested.

Claims 19 – 46 were rejected under 35 USC § 103(a) as being unpatentable over GB 1,480,175.

The present invention is directed to a surface modified powder, which is obtained by thoroughly blending an active agent with a surface modifying material, without the use of a solvent such as water. The flowability of the obtained surface modified powder becomes at most 42° when measured by the angle of repose. Applicants discovered that high flowability can be achieved **without the use of any solvent such as water.** The resultant surface modified powder enables direct tableting and provides a material to prepare an excellent fast disintegrating tablet. This property of fast disintegration at the appropriate time is very desirable. The excellent properties of such tablets is further described in the applicants' article attached hereto (Kato et al., *J. Pharm. Sci. Technol., Jpn.* 62:87-94 (2002)).

Flow properties of solid pharmaceutical compositions are usually determined by measuring the angle of repose. Anyone skilled in the art would readily appreciate that an angle of repose of at most at 42° is an indication of a highly flowable material.

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In contrast, GB 1,480,175 (the '175) describes coated tablets where the pharmacologically active agent must be mixed with maltose, as claimed for example in claim 1. The '175 is restricted to direct compression of the maltose-containing mixture into a tablet. The novel aspect of the '175 is the use of maltose; nothing teaches or suggests a preparing a fast-disintegrating tablet in the absence of a solvent, let alone a powder having a flowability of at most 42° in terms of an angle of repose. Thus, the '175 in no way makes it obvious to exclude the use of a solvent in preparing a fast-disintegrating tablet. Accordingly, applicants respectfully request that the rejection under 35 USC § 103 (a) over GB 1,480,175 be withdrawn.

Claims 19 – 46 were rejected under 35 USC § 103(a) as being unpatentable over JP 10114655 (abstract).

Nothing in JP 10114655 teaches or suggests that its process for preparing a fast disintegrating tablet could be performed in the absence of a solvent, in contrast to the claimed invention. JP 10114655 teaches no more than a conventional method for formulating a solid pharmaceutical preparation, wherein **water is used as a solvent** to prepare a granulated product. Indeed, all of the Examples describe a conventional manner for formulating a tablet by mixing and granulating the medicine, additive and disintegrating agent in the presence of water in a mixing granulator and compressing the granulated product to formulate the tablet.

Similarly, unlike the powder of the present invention, it would not have a flowability as required by the claims. Therefore, JP 10114655 neither teaches nor suggests the surface modified powder of the present invention which is prepared without the use of any solvent such as water. Therefore, applicants respectfully request that the rejection under 35 USC § 103 (a) over JP 10114655 be withdrawn.

In view of the foregoing, applicant respectfully submits that all claims comply with 35

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U.S.C. § 103(a) and are in condition for allowance. Early and favorable action is requested.

In the event that any additional fee is required, please charge Deposit Account No. 50-0850.

Respectfully submitted,

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Ronald I. Eisenstein, Reg. No. 30,628
Nicole L.M. Valtz, Reg. No. 47,150
NIXON PEABODY LLP
101 Federal Street
Boston, MA 02110
(617) 345-6054/1270

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